

Claims 1-5).

REMARKS

The Restriction Requirement

The pending claims, claims 1-7, 10, 12, 14, 16-34, are subject to a restriction requirement in which the claims were assigned to 31 different groups, i.e., more groups than there are claims. It is submitted that this Requirement is in error and should be modified, as follows.

Request for Reconsideration

Applicants request reconsideration of the second restriction requirement, insofar as it is inconsistent with the provisions of the partial waiver of 37 C.F.R. § 1.141 for nucleotide sequences and is contradictory with respect to MPEP § 803.04, which states in pertinent part:

[To] further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide

sequences will be examined in a single application without restriction. [Emphasis added.]

Given the Office's policy with respect to examination of applications containing independent and distinct nucleotide sequences, Applicants respectfully traverse the Requirement as to Groups VII-XIV as inconsistent with the partial waiver of 37 C.F.R. § 1.141 for nucleotide sequences. Indeed, under the partial waiver and Office policy, Applicants may have up to ten independent and distinct nucleotide sequences examined in a single application without restriction.

Respectfully, Applicants disagree with the Examiner's interpretation that the partial waiver of 37 CFR § 1.141 does not apply to situations where the claimed nucleotide sequences are known to encode different proteins with inherently different functions. To the contrary, situations in which one application contains nucleotide sequences encoding different proteins with different functions is precisely the subject matter that the partial waiver § 1.141 seeks to encompass: Independent and distinct nucleotide sequences. See MPEP § 803.04. In effect, the Examiner's present restriction grouping invalidates the express intention that the partial waiver apply to Applicants' application which contains less than ten nucleotide sequences that encode different proteins.

Moreover, Applicant's invention is not of the "exceptional" nature noted as possibly falling outside the ambit of the partial waiver. For example, Applicants do not claim "protein amino acid sequences reciting three dimensional folds." *Id.* Furthermore,

because the sequences in the instant application are encoded by the same virus and from the same reading frame, Applicants submit that the nature of these sequences are not so extraordinary to render the application exceptional and to require individual restriction corresponding the individual sequences.

In this case, Applicants respectfully request that the Office follow the Commissioner's specific intent in establishing Office policy to allow for examination of multiple independent and distinct nucleotide sequences in a single application. The premise to allowing examination of multiple sequences in a single application is "to simplify and standardize PTO policies and procedures and to encourage and promote the growth of this [biotechnology] industry for the benefit of humanity." See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). Limiting the number of sequences examined in a single application serves as a compromise between the burden on the Office in examining multiple sequences and the opportunity for Applicant to submit a reasonable number of sequences in one application for examination. Thus, the present restriction requirement to individual specific nucleotide sequences operates as *de facto* nullification of the partial waiver to 37 C.F.R. § 1.141.

As amended, groups VII-XIV of the present application involve claims 6, 7, 10, 12, 14, 16-31 and describe only eight independent and distinct nucleotide sequences (UTR-1, [SEQ ID NO: 2]; UTR-2 [SEQ ID NO: 14]; a nucleotide sequence encoding a

242-248 kDa polyprotein [SEQ ID NO: 3]; a nucleotide sequence encoding a proteinase [SEQ ID NO: 4]; a nucleotide sequence encoding a methyltransferase [SEQ ID NO: 6]; a nucleotide sequence encoding a helicase [SEQ ID NO: 8]; ORF1b [SEQ ID NO: 10]; ORF11 [SEQ ID NO: 12]). Therefore, Applicants submit that they are in compliance with the partial waiver and request that the restriction requirement be modified to combine groups VII-XIV into one new group I, which Applicants intend to elect.

Furthermore, Applicants submit that the restriction requirement regarding groups XXV-XXXI should be modified to be combined in one new Group II. Each of the groups XXV-XXXI are drawn toward the same claim (claim 34) and the same method of detecting nucleotide sequences that are enumerated in Claims 7, 10, 12, 14, or 16-18. Further, since the method of detection for each of the groups XXV-XXXI are classified similarly (class 435, subclass 6), it would not be an undue burden on the Examiner to evaluate this claim in one new group. See MPEP § 803. Similarly, Applicant submits that the restriction requirement regarding groups XV-XIX should be modified to be combined in one new group III. Each of the groups XV-XIX are drawn toward the same claim (claim 32) of antibodies against polypeptides encoded by the same GLRaV-3 genome. Thus, the groups are related rendering collective examination. The antibodies are raised against the same group of proteins, encoded by the same, larger, nucleotide sequence, and are classified in the same class and only two subclasses. Thus, it would not be an undue burden on the examiner to evaluate this claim as one group. See MPEP

§ 803.

Moreover, since the same method of detection is drawn in each of groups XX-XXIV, these groups should be modified to be combined in one group IV. Each of the groups XX-XXIV are drawn toward the same claim (claim 33) and the same method of detecting antibodies that recognize polypeptides encoded by the same GLRaV-3 genome. Thus, the groups are related rendering collective examination. Further, each of the groups XX-XXIV are classified in the same class and only three subclasses. Thus, it would not be an undue burden on the Examiner to evaluate this claim in one new group. See MPEP § 803.

Applicants submit that Groups I-VI, drawn to polypeptides encoded by the GLRaV-3 genome are related and, therefore, should be examined together. These polypeptides are all encoded by the same, larger, nucleotide sequence and are classified in only two classes. Further, proteinase, methyltransferase, and helicase are encoded by the same reading frame of GLRaV-3 and are classified in the same class and subclass.

Applicants submit that, because these polypeptides are classified in two classes, examining them together would not impose an undue burden on the Examiner. See MPEP § 803. Applicants request that the restriction be modified to combine groups I-VI into a new group V.

CONCLUSION

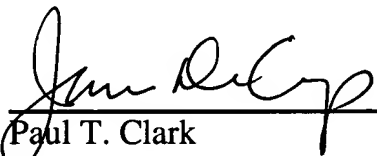
Applicants request that the claims be regrouped as follows: Group I - Examiner's Groups VII-XIV (Claims 6, 7, 10, 12, 14, and 16-31); Group II - Examiner's Groups XXV-XXXI (Claim 34); Group III - Examiner's Groups XV-XIX (Claim 32); Group IV - Examiner's Groups XX-XXIV (Claim 33); and Group V - Examiner's Groups I-VI (Claims 1-5). Applicants intend to elected Group I of this modified grouping.

Applicant notes that a supplemental IDS and forms 1449 were filed on October 5, 1999, January 3, 2001, and May 23, 2001 and request that the initialled form 1449 be returned.

If there are any charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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